K123902



**Section F 510(k) Summary**

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SEP 13 2013

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Trade Name: Physical Monitoring Registration Unit –S (PMRU-S)

Common Name: EMG

Classification Name: Diagnostic Electromyography (890.1375)

Product code: IKN

Class II

Legally Marketed Predicate Device to which we are claiming equivalence: Physical Monitoring Registration Unit (PMRU) K022719, Class II

Description of Device:

The Physical Monitoring Registration Unit-S, (PMRU-S) like the legally cleared PMRU combines surface EMG with functional capacity sensors range of motion, grip and pinch strength sensors. This integration allows for a reproducible, objective interpretation of muscle function and effort via the range of motion, fce, pinch and grip. All muscle groups of the body from cervical (to mid back, low back and extremities can be monitored with the device). Bilateral muscle testing is done to compare antagonist and agonist muscle groups. The devices monitors bilateral muscle activity with the force produced by the patient while he or she pulls on the strain gauge, with the range of motion. is to provide non-invasive muscle testing integrating with range of motion, functional capacity of lifting, pulling, pushing, pinching and gripping. To measure surface emg along the spine, extremities or cervical region. To measure the EMG with functional tasks, to measure the EMG with range of motion, to measure the EMG with pinch and or grip. This this is identical to the already cleared PMRU.

The PMRU-S

- has the same intended use as the predicate;

- has the same technological characteristics as the predicate; has the same intended use as the predicate;
- The PMRU-S uses all the same technological characteristics, it uses the same strain gage, grip, pinch and EMG sensors. The only difference from a technological characteristic is the data is transmitted via Bluetooth.

Indications For Use:

Surface Electromyography with range of motion functional capacity assessment grip and pinch strength.

Intended Use

The Intended Use Section is identical to the original device PMRU (K022719) To provide non-invasive muscle testing integrating with range of motion, functional capacity of lifting, pulling, pushing, pinching and gripping. To pinpoint muscle activity during movement objectively isolating abnormal movements with abnormal muscle patterns. To establish relative functioning of muscle in any specific anomaly that may occur due to muscle damage, muscle fatigue, hypertonicity or stress. To pinpoint referred pain pattern associated with cervical, thoracic, lumbosacral upper and lower extremities, and refer pain sources. To evaluate a baseline muscle activity for pre-employment screening, sport medicine. To look at chronic vs. acute muscle function and range of motion to ascertain good effort with FCE, range of motion, and gripping, and pinch. To ascertain the ischemic activity of muscles. To ascertain chronic damage to muscles. To monitor the frequency range for cardiac muscle.

System Comparisons

| | PMRU | PMRU-S |
|---|---|---|
| EMG leads | 6" clip to snap | 6"clip to snap |
| Strain gage pinch/fce | Force measuring platform | Force measuring platform |
| grip | Jamar dynamoter | Jamar dynamoter |
| Sample rate | 1000 HZ | 1024 HZ |
| CMRR | >90db (at 10 hz) | >90db (at 10hz) |
| Filters | Current limiting | Current Limiting |
| EMG | The instrumentation amplifiers stage detects the voltage difference | The instrumentation amplifiers stage detects the voltage difference between the two (2) points of electrodes on the |

| | | |
|---|---|---|
| | between the two (2) points of electrodes on the patients skin with 1 universal ground | patients skin with ground on each EMG sensor |
| DAQ | The DAC module converts analog voltage to a digital value, which is then passed through an optical isolation device and is then available for processing by the lap top computer. The DAQ is housed in the main circuit board and box for all sensors | The DAC module converts analog voltage to a digital value. This DAQ module is housed in each individual sensor. Since the patient is not connected to a power source no optical isolation is needed. |
| Power Source | 110V AC power from any conventional outlet. | Battery Operated |
| Data transmission | USB or PCMCI cable | Bluetooth |

The PMRU-S is substantially equivalent to the PMRU cleared in K022719 based on the following similarities:

A laptop computer to acquire data

Surface electrodes with range of motion, functional grip and pinch sensors

Data acquisition converting analog to digital signals.

There has been a change to the original device. This is a change for the data transfer to a wireless (Bluetooth) platform. None of these modifications including the Bluetooth data transfer, which is the subject of this submission lead to a change in the indications or intended use of the original device nor do they alter the fundamental scientific technology or introduce a fundamentally new scientific technology. Furthermore, none of these modifications poses an new issues with safety or efficacy. The design change which is the is to transfer the data to host computer without a cable and to further increase the device's safety through use of a battery operated wireless sensors and Bluetooth wireless technology to eliminate any possible connection between the patient and line voltage.

Both PMRU and PMRU-s conform to 60601. In addition, validation tests were performed to validate the accuracy and repeatability of the EMG, Range of Motion, FCE, Pinch and Grip Sensors. It was show through validation using weights for FCE, Pinch, and Grip, inclinometer testing for Range of Motion, and Signal Generator for EMG Sensors. It was

shown through this validation testing that all sensors captured data accurately and repeatability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 13, 2013

OKTX, LLC
c/o Ms. MaryRose Cusimano-Reaston
7225 S 85th E. Ave.
Suite 300
Tulsa, OK 74137

Re: K123902
Trade/Device Name: Physical Monitoring Registration Unit-S (PMRU-S)
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic Electromyograph
Regulatory Class: Class II
Product Code: IKN
Dated: August 9, 2013
Received: August 12, 2013

Dear Ms. MaryRose Cusimano-Reaston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K123902

Device Name: PMRU-S (Physical Monitoring Registration Unit-S)

Indications For Use:

Surface Electromyography with range of motion,functional capacity assessment, grip and pinch strength.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K123902